UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,817	03/07/2006	Russell Mumper	050229-0447	8574

20277 7590 08/22/2007

MCDERMOTT WILL & EMERY LLP
600 13TH STREET, N.W.
WASHINGTON, DC 20005-3096

EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,817	MUMPER ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *9 and 15-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 7/9/07.

Applicant's election with traverse of Group 1 is acknowledged. Traversal is on the grounds that it would not be an undue burden to search additional inventions. This is unpersuasive because search burden is not a criterion for restriction under 35 USC 372. Under 35 USC 372, a lack of unity analysis carried out in accordance with the PCT Rules. The claimed inventions lack unity of invention for the reasons set forth in the restriction requirement, i.e. failure to make a contribution over the prior art. Therefore the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 9 and 15-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/9/07.

Claims 1-26 are pending in the application.

Claims 1-8 and 10-14 are under consideration.

Priority

The instant application is the national stage of PCT/US03/29536, filed 9/24/03 which claims benefit of US Provisional Application 60/412,780, filed 9/24/02. The provisional application fails to provide support for nanoparticles that are not cationic, such as those embraced by instant claims 1, 3-8, and 10-14. Accordingly the effective

filing date of claims 1, 3-8 and 10-14 is 9/24/03. The effective filing date of claim 2 is 9/24/02.

Claim Objections

Claims 1-7 and 10-14 are objected to because they read on non-elected subject matter, i.e. nanoparticles comprising an immunogenic antigen.

Claim 10 is objected to. Insertion of a space between 'd' and 'm' in "andmonophosphoryl" is recommended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by. another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-8, 13, and 14 are rejected under 35 U.S.C. 102(b) and (e) as being anticipated by Felgner et al (US 5,264,618).

Felgner taught compositions comprising complexes of nanoparticulate liposomes and nucleic acids encoding immunogens (i.e. nucleic acid vaccines), and their use to stimulate immune responses with coadminstration of an adjuvant. See abstract; column 7, lines 39, 40, and 49-56; column 8, lines 5-8; column 15, lines 39-43; column 18, lines 30-33, and 43-53. The liposomes must contain cationic lipids, and can also contain neutral (e.g. phosphatidylethanolamine) and/or anionic lipids (see column 14, lines 27-33). These lipids are considered to be surfactants because they are amphiphilic. Absent a limiting definition in the instant specification, the term "oligonucleotide" is considered to embrace the antigen encoding nucleic acids of Felgner.

Claims 1, 8, 10, 11, 13, and 14 are rejected under 35 U.S.C. 102(b) and (e) as being anticipated by Langer et al (US 20020131951, published 3/19/02).

Langer taught compositions comprising an adjuvant such as cholera toxin and cationic nanoparticles comprising a nucleic acid encoding a polypeptide antigen. See abstract and paragraphs 37, 90, 91, and 99. The nucleic acid can be DNA or an oligonucleotide, see paragraphs 11 and 39. Absent a limiting definition in the instant specification, the term "oligonucleotide" is considered to embrace the antigen encoding nucleic acids of Langer.

Claim 2 is rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Langer et al (US 20020131951).

Langer taught compositions comprising an adjuvant such as cholera toxin and cationic nanoparticles comprising a nucleic acid encoding a polypeptide antigen. See abstract and paragraphs 37, 90, 91, and 99. The nucleic acid can be DNA or an oligonucleotide, see paragraphs 11 and 39.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al (US 20020131951, published 3/19/02).

Langer taught compositions comprising an adjuvant such as cholera toxin and cationic nanoparticles comprising a nucleic acid encoding a polypeptide antigen. See abstract and paragraphs, 11, 37, 90, 91, and 99. The nucleic acid can be DNA or an oligonucleotide, see paragraphs 11 and 39.

Langer did not specifically teach neutral nanoparticles.

However, at paragraph 81 on page 10 Langer taught generally that the cationic polymers allowed nucleic acids to pass through membranes by reducing their charge to be neutral or slightly positive. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to use an amount of polycation that

resulted in either neutral or slightly positive nanoparticles when complexed to nucleic acids.

Claims 1, 3, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al (US 20020131951, published 3/19/02) in view of Wolff et al (WO 00/03694).

Langer taught compositions comprising an adjuvant such as cholera toxin and cationic nanoparticles comprising a nucleic acid encoding a polypeptide antigen. See abstract and paragraphs, 11, 37, 90, 91, and 99. The nucleic acid can be DNA or an oligonucleotide, see paragraphs 11 and 39.

Langer did not specifically teach neutral or anionic nanoparticles.

Wolff taught that the charge of polycation/nucleic acid complexes could be adjusted by addition of polyanions, and suggested that this should be done for a variety of reasons including the fact that non-specific binding of cationic particles hinders cellular targeting (i.e. since cell membranes tend to be negatively charged, cationic particles tend to bind without specificity), and the fact that positive charge has an adverse effect on biodistribution of complexes in vivo. See page 4, lines 22-25 and page 18, lines 18-22. Wolff taught that the net charge of the recharged complexes could be positive, negative, or neutral. See page 17, lines 22-24.

It would have been obvious to one of ordinary skill in the art at the time of the invention to readjust the charge of the complexes of Langer, according to the teachings

of Wolff in order to obtain the advantages disclosed by Wolff, e.g. more specific targeting, and improved biodistribution.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al (US 20020131951, published 3/19/02) as applied to claims 1 and 3 above, and further in view of Deng (US 6,667,295).

Langer taught compositions comprising an adjuvant such as cholera toxin and cationic nanoparticles comprising a nucleic acid encoding a polypeptide antigen. See abstract and paragraphs, 11, 37, 90, 91, and 99. The nucleic acid can be DNA or an oligonucleotide, see paragraphs 11 and 39.

Langer did not specifically teach the use of monophosphoryl lipid A as an adjuvant.

Deng taught that either cholera toxin or monophosphoryl lipid A were suitable adjuvants for use with DNA vaccines. See column 25, lines 19-29.

MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness. Thus it would have been obvious to one of ordinary skill in the

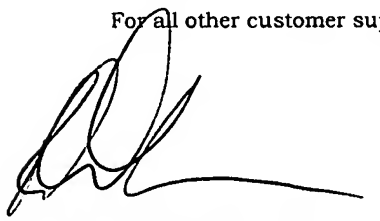
art at the time if the invention to substitute monophosphoryl lipid A for cholera toxin as an adjuvant in the invention of Langer.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.



Richard Schnizer, Ph.D.
Primary Examiner
Art Unit 1635